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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,783	05/02/2002	John C. Herr	00415-03	8483

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UNIVERSITY OF VIRGINIA PATENT FOUNDATION
1224 WEST MAIN STREET, SUITE 1-110
CHARLOTTESVILLE, VA 22903

EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,783	HERR ET AL.	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,9-19,33-36 and 38-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-7, 9-19, 33-36 and 38-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 13 December 2004 is acknowledged and has been entered. Claims 4, 8, 20-32, and 37 have been cancelled. Claims 1-3, 5-7, 9-19, 33-36, and 38-42 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The specification is objected to and claims 5, 6, 13, 14, and 41 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that applicant provides insufficient written description and guidance (i.e. enablement) for how one uses the conjugates as claimed.

Applicant's arguments, the declaration of Thomas R. Moench under 37 CFR § 1.132, and applicant's arguments drawn thereto, filed 13 December 2004 have been fully considered but they are not deemed to be persuasive. Applicant's response, and the opinions in the declaration of Thomas R. Moench, urge that applicant was in possession of, and one would know how to make and use, conjugates as claimed based upon the instant written description and knowledge in the art. The passages in the specification cited by applicant are the suggestion in the specification to form such conjugates, noted by the examiner in the rejection of record, and passages drawn to the use of the unconjugated antibody as a spermicide. The publications representative of knowledge in the art discussed in the declaration are drawn to the therapeutic topical vaginal use of unconjugated antibodies specific for infectious agents or the therapeutic

use of a buffering gel in the absence of any targeting antibody. Such disclosures and arguments are not found persuasive because they are incommensurate with the invention as claimed in which toxins, microbicides, or virucides are conjugated to, and targeted with, an anti-sperm antibody. Such disclosures and arguments are also unpersuasive because they are of no moment with regard to the issues raised in the rejection of record that there was and is no description or guidance for any condition amenable to treatment in which toxin, microbicide, or virucide agents are targeted by conjugation with a sperm-specific antibody, that one would not readily know for what condition a conjugate of a sperm-specific antibody with toxins, microbicides, or virucides would predictably function, other than delivery of a spermicidal toxin, or that one would not be apprised of predictable and appropriate delivery and other properties for such a conjugate for an unspecified condition, in the absence of further description and guidance from applicant. Notwithstanding applicant's assertions and the opinions in the declaration of Thomas R. Moench to the contrary, a mere statement that a particular composition is part of the invention in the absence of any description and guidance for how that composition is predictably used does not satisfy the requirements of 35 U.S.C. § 112, first paragraph. The rejection is maintained.

Claims 1-3, 7, 9-12, 15-19, 33-36, 39, 40, and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Herr et al. (US 5,830,472) in view of Owens et al. (J. Immunol. Meth. 168: 149, 1994) and Bird et al. (Science 242: 423, 1988) for reasons of record.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herr et al. in view of Owens et al. and Bird et al., and further in view of Russell et al. (U.S. Pat. No. 6,080,560) for reasons of record.

Applicant's arguments, the declaration of Thomas R. Moench under 37 CFR § 1.132, and applicant's arguments drawn thereto, filed 13 December 2004 have been fully considered but they are not deemed to be persuasive. The rejection is maintained.

Applicant's response, and the opinions in the declaration of Thomas R. Moench, urge that one would not have been in possession of the sequence of the S19 monoclonal antibody because of the sequencing errors in Herr et al. (US 5,830,472) reported in the instant application. These are not found persuasive for reasons of record, particularly because the reference of Herr et al. teaches the S19 monoclonal antibody which has, and is encoded in the deposited hybridoma by, sequences identical to those as instantly claimed. As set forth, one in possession of the deposited hybridoma and, regardless of the published sequence in the reference, guided by the teachings of the combined references and their conventional methodologies would have isolated and cloned those encoding sequences from the hybridoma as desired by Herr et al. having sequences identical to those as instantly claimed. The deposited hybridoma provides sufficient description and enablement for the inherent sequences of the antibody.

Applicant's response, and the opinions in the declaration of Thomas R. Moench, urge that there is no motivation to combine the references. In response to applicant's arguments and Dr. Moench's opinion, the examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed.

Cir. 1992). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, for the reasons of record, ample motivations to provide a recombinant S19 antibody, even one lacking sites or domains, is provided by the direct suggestion of Herr et al. to do so to meet the goals of the invention and by the benefits taught by Owens et al. and Bird et al., such as to provide a more stable, higher-yield, and/or lower cost production means for the monoclonal antibodies than hybridomas and to provide antigen-binding reagents for applications with lower background non-specific binding, reduced immunogenicity, rapid clearance, or better penetration, and, for the reasons of record, one would have been motivated to specifically select plant host cells for the benefits taught in Russell et al.

Applicant's response, and the opinions in the declaration of Thomas R. Moench, also urge that examples in Owens et al. teach away from the use of single chain antibodies. These are not found persuasive for the reasons of record in view of the benefits taught for the use of single chain antibodies for conjugate applications with effector molecules, clinical applications in particular. There is nothing to indicate that the diagnostic or other uses suggested for the S19 antibody require bi-valent binding, other than its use as a spermicide which causes sperm agglutination, and the reference of Owens et al. also teaches means for scFv molecule modifications to allow multivalent binding therewith, if required.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James L. Grun, Ph.D.
April 1, 2005

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
4/2/05